ALERTBULLETIN®

CNA
We can show you more.®

AB 2016 ISSUE 3

Direct Access Testing: An Update on the Revised CLIA Regulations

In February 2014, the U.S. Department of Health and Human Services (HHS) amended the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. Prior to the change, patients generally were required to obtain their test results from the ordering physician. The revised regulations give patients or their designees the right to obtain test reports directly from laboratories, upon request. The final rule also eliminates a previous exception under the HIPAA Privacy Rule applying to both CLIA-certified and CLIA-exempt laboratories regarding a patient's access to protected health information (PHI).[1]

The new rules reflect the rapid growth in direct access testing (DAT), which is generally defined as patient-authorized medical testing without a prior physician consultation, often via dedicated walk-in laboratories. While DAT boosts efficiency and empowers consumers, it also creates a credible risk of delayed or incorrect diagnosis, as abnormal or out-of-range results may be interpreted without the benefit of professional guidance. Other potential problems include lapses in continuity of care and medical management. Laboratories must be aware of DAT exposures and examine their policies and procedures to ensure compliance and address patient safety concerns.

The 2013 CNA publication "Laboratories and Direct Access Testing: Regulations, Resources and a Checklist of Safeguards" describes the then-upcoming changes to direct access testing rules and discusses associated risk exposures. This *AlertBulletin*® reviews the practical implications of the final rule and suggests additional risk management safeguards.

PRACTICAL IMPLICATIONS

The final regulation amends the HIPAA Privacy Rule to the effect that CLIA-certified and CLIA-exempt laboratories, as with other covered entities, are now legally obligated to provide individuals with access to their PHI. (However, laboratories not subject to the Privacy Rule are not required to provide patients with access to their test reports.[2]) The requirement preempts state restrictions that may affirmatively restrict patient access to laboratory test results or otherwise require an ordering provider's consent.

Under the rule, medical laboratories may not deny individuals, including those with mental illness, access to test results or reports based upon the sensitive nature of the information or its potential for causing distress. A limited exception exists for cases where a licensed healthcare provider determines, in the exercise of professional judgment, that access is reasonably likely to endanger the life or safety of the requesting consumer or another individual. In that case, the requester may seek a review of the denial decision by an unaffiliated healthcare professional.

The right of access extends to test results and other information about the patient contained within a designated record set, even if the information is stored off-site or was created before the effective date of the final rule (i.e., October 6, 2014). Laboratories have 30 days to respond to a request. If more time is needed to retrieve an archived record, the laboratory may request one 30-day extension, as long as it provides the reason for the delay in writing to the requester.

Before releasing test results, laboratories must verify patient identity. The amended regulation does not mandate any specific process, but it does cite the verification standard in the Privacy Rule, thus invoking the concept of "reasonable discretion." Such discretion may include photo identification where the patient/designee requests test results in person, or the use of authentication information when requests are made online, by telephone or in writing. In cases of anonymous consumer-initiated testing (e.g., for HIV and other sexually transmitted diseases), a code number is linked to the test result and laboratory slip, thereby permitting individuals to obtain results online or via telephone without supplying their name. Anonymous test sites are not obligated to mail a written record of the results to a requesting consumer.

The final rule does not specify particular formats for requesting and accessing test results. However, assuming that the process will be guided by HIPAA Privacy Rule standards, the patient would be required to make the request in writing or via portal and possibly pay for the cost of copying and mailing, as well as any electronic media utilized, such as a CD or flash drive.[3] With respect to report content, laboratories are required neither to interpret laboratory test results for the patient nor to include a statement advising the patient to seek the counsel of the ordering provider.

1 CLIA-certified laboratories are subject to a rigorous certification process in order to ensure that sterile, state-of-the-art testing processes are followed. Veterans Administration, public health, forensic, research and teaching laboratories are exempt from CLIA regulations. Patients performing tests in their own home are also exempt, but residents of nursing or intermediate care facilities are not.

2 A laboratory is considered a covered entity under HIPAA if it conveys patient PHI in electronic form, e.g., by electronically transmitting healthcare claims to a health plan, requesting prior authorization from a health plan or inquiring about a health plan's coverage for a specific individual.

3 The Office of Civil Rights has issued guidance on how to calculate actual and average costs for copies of electronic PHI, and opines that organizations may instead opt to charge a flat rate of $6.50 for this service.

ADMINISTRATIVE SAFEGUARDS

The following measures, which are based upon the HHS final rule as well as industry practices, are designed to help laboratory administrators comply with the new regulations:

Update written Notice of Privacy Practices. Affected laboratories should review their HIPAA Notice of Privacy Practices (NPP) and update it if necessary, in order to inform individuals of their rights under the amended regulations, as well as current procedures for obtaining laboratory results. Laboratories should further review any general policies and procedures regarding release of information, such as request denial and denial review procedures, and rescind any provisions and/or marketing statements that exempt PHI in laboratory records from release or that prohibit direct disclosure of test results without physician authorization. For additional guidance on NPP updates and a link to sample HIPAA notices, see the HIPAA Compliance Reminder.

Streamline request procedures. In general, individuals should be able to obtain their test results by requesting them in writing or via patient portal from the laboratory's HIPAA privacy officer. Hospital-based laboratories are advised to align their procedures with the hospital's overall record request process to strengthen compliance and diminish exposure to complaints and appeals.

Educate staff about the new regulations. Laboratory personnel who manage test result requests should be informed of the revisions and their effect on day-to-day practice.

Document the reason for delays. As previously noted, if a CLIA laboratory cannot issue a test report in 30 days, it must notify the requesting party in writing of the cause of the delay and document this action. HIPAA does not preempt more stringent state laws, so laboratory administrators should be aware of all relevant regulations regarding access provisions and response times, and revise written policy accordingly.

Eliminate mandatory wait periods. In the final rule, HHS declined to recommend that laboratories delay responding to a patient request to ensure that ordering providers receive the report first. The single 30-day extension currently permitted is considered sufficient time for laboratories to provide test reports to the ordering provider prior to patient receipt. In addition, laboratories should if possible encourage providers to discuss test results with patients, ideally before the patient receives a copy.

Issue simple, clearly written advisory statements with the test results. Although advisory statements are not required, laboratories should consider including messages about the need to consult a physician regarding interpretation of results and associated clinical questions. This practice may substantially improve the defense posture of both laboratories and providers in the event that delayed response to abnormal results leads to patient harm. Moreover, in its policy statement on direct access testing, the American Society for Clinical Pathology recommends that laboratories present test results in easily interpretable form, and include explanatory material written at an appropriate reading level. Records should be kept of all patient communications, and internal policy and procedure documents should be archived.

The 2014 CLIA amendment creates both opportunities and risks for medical laboratories. Administrators should examine written policies to ensure that they fully reflect the regulatory changes, protect consumers' rights and enhance safety.

QUICK LINKS

- "The Cost Effective Laboratory." *COLA's Insights*, from the Commission on Office Laboratory Accreditation, March/April 2015. (Scroll to page 14.)
- "Direct-to-Consumer Laboratory Testing." Position statement of the American Association for Clinical Chemistry, issued July 2015.
- Swain, M. and Patel, V. "Patient Access to Test Results Among Clinical Laboratories." *ONC Data Brief*, from the Office of the National Coordinator for Health Information Technology, Number 13, February 2014.

Would you like to read *AlertBulletin*® online? Visit **www.cna.com/healthcare**, click on "Search CNA" in the top right-hand corner of the screen, type the article's full title in the search box and then click on the magnifying glass icon.

CNA

For more information, please call us at 888-600-4776 or visit www.cna.com/healthcare.